







Attachment 1



APPENDIX: COLLECTED EXCERPTS FROM FDA QUALITATIVE STUDIES

“Erectile Dysfunction” Warning	
Warning/ Image	Excerpted Consumer Responses/Study Commentary
Draft Image: 	<ul style="list-style-type: none"> Study Commentary: “Make it clear that the man’s emotion is shame, not fatigue or body aches.” [Second Qualitative Study at 20, 165]
Near-Final Image:¹ 	<ul style="list-style-type: none"> Study Commentary: <ul style="list-style-type: none"> “Participants had a wide variety of interpretations for this image.” <ul style="list-style-type: none"> “The couple could have a strained relationship. One participant thought conflict could be caused because he smokes and she doesn’t.” “Insomnia/sleeplessness” “Stress/depression” “In one group participants discussed the fact that the man looks older than the woman. This could be due to smoking.” “Many participants agreed that without the words, it was difficult to know what the image was depicting.” “Some participants thought they have been trying to have kids and couldn’t.” “Some participants noted that the couple doesn’t have a happy relationship; they appear to be unhappy or upset.” <p>[Third Qualitative Study at 70, 72]</p>
“Neck Tumor” Warning	
Warning/ Image	Excerpted Consumer Responses/Study Commentary
Draft Image: 	<ul style="list-style-type: none"> Study Commentary: <ul style="list-style-type: none"> “It wasn’t clear what the message was even when the tumor was identified.” “This image is a good candidate for deletion.” Consumer Responses: <ul style="list-style-type: none"> “Kind of disgusting.” “[L]ooks like there’s an older woman in miserable pain.” “No, not clear. Like, what exactly is that?” “A little confusing — a person might think it could be something else.” <p>[Second Qualitative Study at 61–63, 65, 161]</p>

¹ In this study, participants were shown the image by itself, as well as image/statement pairings. Third Qualitative Study at 6. Some of the cited comments pertain to the image; others pertain to the image and text together.

<p>Near-Final Image:</p> 	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ “Some participants thought the lump was too large to be realistic. One participant remarked that it was not realistic because a person would have a tumor removed before it became that large.” ○ “Making the lump smaller would make this image more realistic.” <p>[Third Qualitative Study at 30]</p>
<p align="center">“Diseased Feet” Warning</p>	
<p>Warning/ Image</p>	
<p>Textual Warning: “Smoking Causes Gangrene, Buerger’s Disease, and Diabetes, Which Can Lead to Amputation of Limbs”</p>	<p align="center">Excerpted Consumer Responses/Study Commentary</p> <ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ “Many participants did not think the statement was believable.” ○ “Other participants were confused about the association between diabetes or gangrene and smoking because they knew each to be caused by other things than smoking.” <p>[First Qualitative Study at 43–44]</p>
<p>Draft Image:</p> 	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ “Clarity of message: Low” ○ “It was clear to all participants that the subject ... was missing some toes, but the reason why or how was unclear.” • Consumer Responses: <ul style="list-style-type: none"> ○ “It grabbed my attention because it’s probably one of the grosser pictures.” ○ “the shock value” ○ “It’s powerfully disturbing.” ○ “That really just disgusts me.” ○ “If you want to look at your feet with 5 toes, then you shouldn’t smoke.” ○ “Smoking will cause me to get fingers, toes amputated.” ○ “Does this mean I won’t be able to walk?!” ○ “It’s confusing... I don’t know how smoking is related to toes.” ○ “It’s not clear.” <p>[Second Qualitative Study at 126, 128, 130]</p>
<p>Near-Final Image:</p> 	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ “The idea of losing limbs scares some participants and grabs their attention.” ○ “Some participants were still confused about why some toes were missing and some were black or red.” ○ “Make the image appear less severe.” <p>[Third Qualitative Study at 67–68]</p>

"Sick Child" Warning

Warning/ Image	Excerpted Consumer Responses/Study Commentary
<p>Draft Image:</p> 	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ "Clarity of message: Low" ○ "Maintain the look of dismay (e.g., sadness in the eyes)." • Consumer Responses: <ul style="list-style-type: none"> ○ "I'm going to end up in the hospital . . ." ○ "If you smoke, you'll need a ventilator of sorts or a breathing apparatus." ○ "It affects the majority of people with children. So, that's what touches me." ○ "The sadness expressed in the subject's eyes and the oxygen mask grabbed participants' attention." ○ "I see this being duplicated with my kids. It sends me into despair." ○ "It's scary to see that face. The impression it gives me...I feel something that isn't pretty, and unpleasant." ○ "[I]t's sad and memorable." ○ "It works sufficiently cruelly." <p>[Second Qualitative Study at 13, 20, 22, 24, 26, 158]</p>
<p>Near-Final Image:</p> 	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ "Some participants stated that it was unclear what was wrong with the child. Without additional information, participants would not know that the image is associated with smoking." ○ "Reasons it was not realistic were: the child appeared to be too young to be so sick; the image didn't look natural (it looked drawn or photoshopped, especially the tube and mask)...." ○ "[N]ot a realistic outcome of secondhand smoke . . ." <p>[Third Qualitative Study at 14, 16]</p>

"COPD Nasal Cannula" Warning

Warning/ Image	Excerpted Consumer Responses/Study Commentary
<p>Textual Warning: "Smoking Causes COPD, a Serious Lung Disease, and Permanently Scars Lung Tissue"</p>	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ "Similar to their reactions to previous statements, participants reacted negatively to the absence of the word 'can' or 'could' before 'causes.' Because they believed other things could cause COPD, some participants said the statement was too general." ○ "Participants suggested adding 'can' or 'may' to this statement before 'causes' and before 'permanently' as well." <p>[First Qualitative Study at 19]</p>

Draft Image:

- Study Commentary:
 - “While this image did not deliver any new information, it was especially attention-grabbing due to the sadness and pain depicted in the man’s expression.”
 - “Retain the look of misery/sadness/resignation on the man’s face.”
- Consumer Responses:
 - “This guy is miserable, makes you uncomfortable.”
 - “Immediately you see this disgust and just how miserable he is. Well, he looks sad, like a helpless animal.”
 - “Yes, it grabs my attention because he is suffering and because we see this tube. You can see it in his face. This guy is in pain, he is suffering and is sad.”
 - “Kind of scared ... struggling with the fact that he has breathing tubes ... this one doesn’t look very happy either.”
 - “You’ll be on oxygen ... You have to carry that thing around and you have to carry the cord around your house.”
 - “Because you smoke you’ll have trouble breathing and you’ll have to use an air tank.”

[Second Qualitative Study at 38–40, 42, 159]

Near-Final Image:

- Study Commentary:
 - “The person in the image makes the message more personal (someone might connect it with someone they know).”
 - “[S]hows an unhappy person, hooked up to the machine”

[Third Qualitative Study at 44-45]

“Diseased Non-Smoker’s Lungs” Warning

Warning/ Image


Excerpted Consumer Responses/Study Commentary

Textual Warning:



“Cigarettes Cause Fatal Lung Disease”

- Study Commentary:
 - “Many of the adults did not find the statement believable. Their comments suggested that the primary reason they didn’t believe it was that it was too definitive.”
 - “Participants, both adults and adolescents, said that they would find the statement more believable if the word ‘may’ or ‘can’ was inserted before the word ‘cause.’”
 - “One adolescent also said that the threshold for risk should be stated.”
- Consumer Responses:
 - “The minute you pick up a cigarette, you take that drag, you’ve got emphysema.”
 - “You’re going to die from smoking. Smoking kills.”

[First Qualitative Study at 15]

Textual Warning: “Smoking Causes Death from Lung Diseases such as Emphysema and Chronic Bronchitis”	<ul style="list-style-type: none"> • Study Commentary: “One participant said he thought the statement was a ‘scare tactic.’” [First Qualitative Study at 17]
Draft Image: 	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ “Participants were particularly affected by the image’s harsh depiction of a body organ in the palms of a surgeon.” ○ “Participants found [the image] attention-grabbing because of its gruesome depiction and implication of death.” • Consumer Responses: <ul style="list-style-type: none"> ○ “[I]t’s just very dramatic.” ○ “[I]t’s sad and grotesque, and it would make you want to cut down on the cigarettes and then quit.” ○ “I think it’s saying ‘Buy this pack of cigarettes and this is what your lungs will look like in years to come.’” ○ “When you smoke, it damages your lungs and you end up dying earlier than you’re supposed to because you’re smoking.” ○ “Your lungs are going to look like soot.” ○ “[T]his is the perfect image to show somebody who you don’t want to smoke.” <p>[Second Qualitative Study at 33, 35, 37]</p>
“Bloody Urine” Warning	
Warning/ Image	
Excerpted Consumer Responses/Study Commentary	
Textual Warning: “Smoking Causes Bladder Cancer, Which Can Lead to Painful and Frequent Urination”	<ul style="list-style-type: none"> • Study Commentary: “Most adult participants did not believe the statement. As was the case regarding other statements, participants stated that the wording implied that smoking <i>definitely</i> causes bladder cancer, which made the statement less believable.” [First Qualitative Study at 26]
Textual Warning: “Cigarettes Cause Cancer”	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ “Many participants thought the statement was not believable because it said ‘causes’ and not ‘can cause’ or ‘may cause.’ When reacting to the statement, participants commonly pointed out that some people smoke and do not get cancer.” ○ “Participants were generally comfortable with adding a ‘can cause’ or ‘may cause’ to the statement.” • Consumer Response: “It’s false. ‘It may cause cancer’ would be more, or ‘may contribute to’ would be more honest. Just blatantly saying that smoking a cigarette is going to give you cancer, period, end of sentence, is, you know, it’s just not true.” [First Qualitative Study at 22]

"Finger Prick" Warning

Warning/ Image	Excerpted Consumer Responses/Study Commentary
Textual Warning: "Smoking Causes Diabetes"	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ "Some participants pointed out that diabetes is caused by other things besides smoking and that this statement seemed to contradict other information they knew about diabetes." ○ "Some participants thought the statement would be more believable if it said 'may cause' or 'might be a contributing factor.'" • Consumer Response: "I know there's a lot more causes of diabetes other than smoking, and I know not every smoker contracts diabetes, so ... rewording it might be, might make it more believable." [First Qualitative Study at 45]
Draft Image: 	<ul style="list-style-type: none"> • Consumer Response: "I don't understand it." [Second Qualitative Study at 125]
Near-Final Image: 	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ "All groups discussed the fingernails being yellow, crusty, discolored or dirty." ○ "Some participants didn't know what the rating ('175') meant (whether it was high or low). One participant noted that it does say the blood sugar is 'above target' but it's hard to read." ○ "Make the blood look more realistic – it's too much blood." [Third Qualitative Study at 64]

"Cataracts" Warning

Warning/ Image	Excerpted Consumer Responses/Study Commentary
Textual Warning: "Smoking Causes Blindness"	<ul style="list-style-type: none"> • Study Commentary: "Some participants said they would believe the statement if it was less absolute and used 'may cause' or 'can cause.'" • Consumer Response: "Honestly, if they have the same issue with every one that comes up, it's too absolute. It doesn't list smoking as one of the factors or a contributing factor a risk factor—it's too absolute and too simplistic." [First Qualitative Study at 46]



- Study Commentary:
 - “A large number could not glean any health consequences from the image.”
 - “Clarity of Image: Low”
 - “Clarity of message: Low”
- Consumer Responses:
 - “It looks like a sad man....”
 - “It’s not a happy image to me.”
 - “It confuses me....”
 - “I have no idea what they are trying to get at here.”

[Second Qualitative Study at 143-45]

Warning/ Image

Excerpted Consumer Responses/Study Commentary

Draft Image:



- Study Commentary:
 - “The depiction of an underweight newborn was emotionally attention-grabbing to most.”
 - “Participants clearly demonstrated an emotional connection to the image.”
- Consumer Responses:
 - “It saddens me.”
 - “It’s heartbreaking, really.”
 - “It would really creep me out.”

[Second Qualitative Study at 93, 97, 164]

Near-Final Image:



- Study Commentary: “One participant said the phrase ‘stunts fetal growth’ made them wonder if this was a ... baby that is not gaining weight like it should or if it was an infant.”

[Third Qualitative Study at 21, 23]

“Open Heart Surgery” Warning

Warning/ Image



Excerpted Consumer Responses/Study Commentary

Textual Warning:

“Smoking Causes Heart Attacks and Strokes by Clogging Your Arteries”

- Consumer Response: “[S]houldn’t it say ‘it increases your risk’ because people are going to think, well, say they have parents who smoke, they’re going to think, ‘Well, that didn’t happen to them, so it’s not going to happen to me.’”

[First Qualitative Study at 29]

<p>Textual Warning: “Cigarettes Cause Strokes and Heart Disease”</p>	<ul style="list-style-type: none"> • Study Commentary: “Some participants thought the statement is slightly misleading because it says ‘causes’ and not ‘can cause’ or ‘may cause’. When probed, all participants who disliked the use of ‘cause’ thought that the statement would be improved by changing the wording to ‘is a cause of.’” • Consumer Responses: <ul style="list-style-type: none"> ○ “I don’t think that it, it causes, it causes every stroke and heart disease.” ○ “They should put ‘can cause’...because it’s not automatically going to cause a stroke or heart disease, but they can cause stroke and heart disease.” <p>[First Qualitative Study at 27–28]</p>
<p>Draft Image:</p> 	<ul style="list-style-type: none"> • Study Commentary: <ul style="list-style-type: none"> ○ “Clarity of Image: Low” ○ “Clarity of message: Low” • Consumer Responses: <ul style="list-style-type: none"> ○ “The message was unclear, and many didn’t understand what the image was trying to convey.” ○ “[V]isually unappealing.” ○ “I don’t like this at all.... Ugly.” ○ “It’s ugly to see that they cut into the person to see their lungs, and everything is all black, dirty.” ○ “[I]t grabs your attention because the image is ugly, seeing someone with the breast open.” ○ “[I]t’s kind of like this is the reality of what’s going to happen if you smoke cigarettes.” <p>[Second Qualitative Study at 77–78, 81]</p>
<p>Near-Final Image:</p> 	<ul style="list-style-type: none"> • Study Commentary: “Many participants were confused about the scar....” <p>[Third Qualitative Study at 59]</p>